UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA

INTERNATIONAL REHABILITATIVE SCIENCES INC, a Washington corporation, d/b/a RS Medical,

Plaintiff,

v.

SYLVIA M. BURWELL, in her official capacity as Secretary, United States Department of Health and Human Services,

Defendant.

Civil Action No. 08-cv-05442 (BJR)

MEMORANDUM OPINION AND ORDER

I. INTRODUCTION

Before the Court is the motion for summary judgment filed by Plaintiff International Rehabilitative Sciences Inc. (hereinafter RS Medical) and the motion for partial summary judgment filed by Defendant Sylvia M. Burwell, in her official capacity as Secretary of the United States Department of Health and Human Services (the Secretary). Upon consideration of the parties' arguments, the relevant case law, and the entire record, the Court grants Defendant's Partial Motion for Summary Judgment[1] [139] and denies Plaintiff's Motion for Summary Judgment [140].

[1]Defendant's motion is "partial" because, if this Court grants Plaintiff summary judgment on the liability issue, Defendant requests to remand to determine the appropriate payment amount for the specific disputed claims. Although Plaintiff has requested a remand to the Secretary with instructions that the agency pay the supplier based on 80 percent of the amount billed [Doc.# 65 at 1], the Secretary has not made a final decision regarding the amounts to be paid, and, therefore, the Court does not have subject matter jurisdiction to decide this question, as judicial review is limited to the Secretary's final decisions. 42 U.S.C. § 1395ff(b)(1)(A). Given the Court's ruling, however, this issue is moot.

II. PROCEDURAL BACKGROUND

Plaintiff, RS Medical, filed the instant case on July 14, 2008, challenging four decisions by the Medicare Appeals Council (hereinafter MAC) denying coverage by Medicare of the BIO-1000 device. On July 28, 2009, the United States District Court for the Western District of Washington entered summary judgment for Plaintiff and against the Secretary, concluding that the Secretary's final denials of coverage were arbitrary and capricious and not supported by substantial evidence. *Int'l Rehab. Scis, Inc. v. Sebelius*, 737 F. Supp. 2d 1281, 1287-93 (W.D. Wash. 2010). Given its ruling, the District Court did not reach the issues raised by Plaintiff in the instant motion as to whether Plaintiff could shift its liability, specifically, whether Plaintiff knew or had a reason to know that the BIO-1000 would not be covered by Medicare, and whether Plaintiff gave adequate notice to the beneficiaries that the BIO-1000 would probably not be covered by Medicare. *Id. See* 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a) (limited liability statutes).

On appeal, the Ninth Circuit reversed the District Court's grant of summary judgment for Plaintiff. The Ninth Circuit concluded that the Secretary's coverage denials for the BIO-1000 were supported by substantial evidence and were not arbitrary and capricious. *Int'l Rehab. Scis, Inc. v. Sebelius*, 688 F.3d 994, 999-1004 (9th Cir. 2012). The Ninth Circuit remanded the limitation on liability issues. *Id.* at 1004.

In 2010, the limitation on liability issues were raised by the manufacturer of the BIO-1000,[2] BioniCare, in a similar case brought before the United States District Court for the District of Maryland. *Almy v. Sebelius*, 749 F. Supp. 2d 315, 319 (D. Md. 2010). In *Almy*, the District Court concluded that "Plaintiff could not receive shelter from liability under 42 U.S.C. §

[2] The same to questions were: 1) whether BioniCare knew or had a reason to know that the BIO-1000 would not be covered by Medicare; and 2) whether BioniCare provided adequate notices to the beneficiaries that the device would probably not be covered, and, therefore, shifted liability to the beneficiaries. *Almy*, 749 F. Supp.2d at 334-35.

1395pp" because Plaintiff was on notice that the claims would be denied due to the prior negative decisions by Medicare contractors,[3] and because Plaintiff provided notices to the beneficiaries that the device probably would not be covered by Medicare. *Almy*, 749 F. Supp. 2d at 335. In addition, the *Almy* Court upheld the Secretary's decision that Plaintiff provided "generic advance notices" to the beneficiaries, which did not enable the beneficiaries to make an educated decision whether to accept or reject the device, and, therefore, Plaintiff could not shift the liability of non-coverage to the beneficiaries. *Id.* at 334-35. The Fourth Circuit affirmed. *Almy v. Sebelius*, 679 F.3d 297 (4th Cir. 2012).

Presently before the Court are two questions: 1) whether Plaintiff knew or had a reason to know that the BIO-1000 would not be covered by Medicare; and 2) whether Plaintiff provided the beneficiaries with adequate notice that the BIO-1000 would not be covered by Medicare, and, therefore, shifted the liability to the beneficiaries.

III. FACTUAL BACKGROUND

RS Medical, a supplier of durable medical equipment under the Medicare program, distributes the BIO-1000, a device that delivers electronic impulses to the knee joint and is used by individuals with osteoarthritis of the knee. (AR 19,017-18; 20,515). In July 1997, the original manufacturer of the BIO-1000, Murray Electronics, sought clearance from the Food and Drug Administration (FDA) to market the device based on its substantial equivalence to a transcutaneous electric nerve stimulator (TENS) device, and the FDA cleared the BIO-1000 on this basis. (AR 20,513-15). BioniCare Technologies, Inc. (BioniCare) eventually took over manufacture of the BIO-1000, obtained similar clearance from the FDA, and began submitting claims for coverage to Medicare contractors. (AR 20,499-506).

[3] The District Court found that BioniCare was on notice that the BIO-1000 would be covered, even though the Medicare contractors had granted coverage on many other occasions. *Id.* 326-28.

In 2004, BioniCare submitted about 1200 claims to Medicare and commercial contractors, almost all of which were denied. (AR 19,135). In 2005, BioniCare submitted 1700 claims, most of which were also denied. (AR 19,137).

In February 2005, Plaintiff RS Medical contracted with BioniCare to sell the device. (AR 19,138). BioniCare advised RS Medical of the difficulties that BioniCare had with Medicare and that Medicare was not paying claims for the BIO-1000. (AR 19137-38). RS Medical began submitting reimbursement claims to Medicare in July, 2005. (AR 20903). RS Medical billed Medicare $4,425 for a single-knee device and $5,100 for a dual-knee device. (AR 19,133-34). During the same period, the TENS device, which was comparable to the BIO-1000, cost $800. *Int'l Rehab.*, 688 F.3d at 998. In 2005, Plaintiff received denials of coverage on the basis that "[t]he currently published studies in the medical literature do not clearly document the effectiveness of the BIO-1000 in healing osteoarthritis of the knee." (Def.'s M. for Partial Summ. J. at 12). In April 2006, in order to obtain coverage of the device, Plaintiff submitted a letter to the Center for Medicare and Medicaid Services from Senators Arlen Specter and Rick Santorum, which stated that "only one Medicare claim [had been] paid since introduction of the product in 2003." (AR 20,902). A similar letter was submitted in December 2005 from Senator Patty Murray and three other Senators, stating that "many commercial insurers and workers' compensation systems are paying for the device, but that CMS is not." (AR 20,899). In 2006, many claims for coverage of the BIO-1000 were granted coverage "at [the] lower levels of the process," without reaching the MAC. *Int'l Rehab.*, 688 F.3d at 998. When the claims at issue finally reached the MAC through the administrative appeal process, all of them were denied. (AR 89-91, 97, 100, 102, 106-10, 114-15, 117, 119-20, 123; AR 19,239; AR 19,986).

In the four decisions of the MAC at issue in this case, the MAC concluded that there was not enough evidence to establish that "the BIO-1000 was 'reasonable and necessary' for

treatment." *Int'l Rehab.*, 688 F.3d at 998; (AR 48-126; AR 19,228-239; AR 20,008-028). RS Medical had provided evidence that the device was reasonable and necessary in the form of studies conducted by the manufacturer of the BIO-1000, BioniCare, showing that the device was effective at alleviating pain. *Int'l Rehab.*, 688 F.3d at 998 (AR 19,235). RS Medical also had provided evidence in the form of studies showing that the BIO-1000 "was effective at regenerating cartilage in rabbits and cows." *Int'l Rehab.*, 688 F.3d at 998-99; (AR 38-39). The MAC rejected both types of evidence, finding that the studies that purported to demonstrate pain alleviation were conducted by the party with a financial interest in the device, and that the studies that purported to show the regeneration of cartilage were not conducted on humans. *Int'l Rehab.*, 688 F.3d at 998-99; (AR 13-14, 38-39).

If at any level of review it is found that the device is not reasonable and necessary, the Secretary will nevertheless pay the claim if the supplier did not know and had no reason to know that the item would not be covered by Medicare. 42 U.S.C. § 1395pp. 42 C.F.R. §411.400(a) provides that Medicare will pay for the device that was found not reasonable and necessary if "[n]either the beneficiary nor the provider, practitioner, or supplier knew, or could reasonably have been expected to know, that the services were excluded from coverage." The MAC refused to limit RS Medical's liability of the denied claims because it concluded that "RS Medical 'knew or had reason to know that Medicare would not cover the device' because 'its efficacy had not been established in the requisite peer-reviewed literature' and because 'the record does not indicate general acceptance of the device by the medical community.'" *Id.* at 999.

Finally, the MAC refused to allocate the financial risk to the beneficiaries in most of the claims at issue in this case because it concluded that "most of the advance beneficiary notices provided by RS Medical were generic and thus insufficient to shift liability to the beneficiaries." *Id.* Plaintiff challenges these conclusions.

IV. MEDICARE CLAIM PROCEDURE

The Medicare program is set forth in Title XVIII of the Social Security Act (the Medicare Act), 42 U.S.C. §§ 1395, *et seq*. This case arises under Part B of the Act, which is a voluntary supplemental program that insures medical and other health services, including the provision of "durable medical equipment" (DME). 42 U.S.C. §§ 1395j, 1395k(a)(1), 1395x(s)(6). A specific service is covered only if it is not within the scope of any coverage exclusion. 42 C.F.R. § 410.12(a). One such exclusion bars payment for all items and services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). The Secretary has discretion to determine whether a particular medical service is reasonable and necessary. *Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (citing 42 U.S.C. § 1395ff(a)).

In the event that the coverage for DME is denied because it falls within an exclusion (as it has been in this case), Medicare will nevertheless pay the claim if the supplier did not know, and could not reasonably have been expected to know, that the item would not be covered by Medicare. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). In addition, the supplier can also shift the risk of non-coverage to the beneficiary by providing the beneficiary with advance written notice (called an Advance Beneficiary Notice or ABN) containing the specific reason why the item most likely will not be covered. 42 C.F.R. § 411.404(b); (Def.'s M. for Partial Summ. J., Ex. C at 9-11 (Medicare Claims Proceeding Manual ch. 30, § 40.3); Ex. D at 4 (Medicare Claims Proceeding Manual ch. 30, § 50.2.1)). An ABN that is "generic," because it states only that Medicare denial of payment "is possible" or that the supplier "never knows whether Medicare will deny payment," is not sufficient to shift the supplier's liability. (Def.'s M., Ex. C at 17 (Medicare Claims Processing Manual ch. 30, § 40.3.6.1)).

The Secretary, through the Center for Medicare and Medicaid Services (CMS), contracts with private insurance carriers to administer the Part B claims process. 42 U.S.C. § 1395u; 42 C.F.R. § 421.200. DME claims are handled by four "Medicare Administrative Contractors," each covering a different geographic region. 42 U.S.C. § 1395m(a)(12); 42 C.F.R. §§ 421.210(c)(2). To have the claim for DME covered by Medicare, the supplier of DME must electronically submit the claim together with sufficient supporting information to permit a determination regarding coverage and payment. 42 U.S.C. § 1395l(e); 42 C.F.R. § 424.5(a)(6). If the submitted claim is "clean," as defined in 42 C.F.R. § 405.902, the Medicare contractor must issue an "initial determination" on such claim within 30 days of receipt. § 405.922.

A supplier may request a "redetermination" by the same contractor if the contractor's initial determination is unfavorable. 42 U.S.C. § 1395ff(a); 42 C.F.R. §§ 405.920 and 402,940. Then, the supplier may request "reconsideration" by a "qualified independent contractor." 42 U.S.C. §§ 1395ff(b)(1)(A) and 1395ff(c); 42 C.F.R. § 405.960. Next, if still dissatisfied, the supplier may request a hearing before an Administrative Law Judge (ALJ).[4] 42 U.S.C. §§ 1395ff(b)(1)(A) and (d); 42 C.F.R. §§ 405.1000-02, 405.1042, 405.1046. Finally, the claimant may seek review of the ALJ's decision at the last level of the administrative appeal, the Medicare Appeals Council. 42 U.S.C. §§ 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100, 405.1122. The MAC decision (or ALJ decision, if not reviewed by the MAC) represents the final decision of the Secretary. 42 C.F.R. §§ 405.1048, 405.1130, 405.1136.

The claimant then may seek judicial review of the Secretary's decision in District Court. 42 U.S.C. § 1395ff(b)(1)(A).

[4] The Department of Health and Human Services, Office of Medicare Hearings and Appeals.

V. STANDARD OF REVIEW

This Court reviews the Secretary's final decisions under the "arbitrary and capricious" standard of review. Under this standard, as set out by the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 500, *et seq.*, a court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." 5 U.S.C. § 706(2). To meet the requirements of the APA, an agency must "examine the relevant data and articulate a satisfactory explanation for its action." *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1810 (2009) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). An agency acts arbitrarily and capriciously where "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicles Mfrs. Ass'n of U.S., Inc.*, 463 U.S. at 43. This Court's review of the action "must be searching and careful, but the ultimate review is a narrow one." *Marsh v. Oregon Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotations and citation omitted).

Summary judgment is appropriate when the pleadings and the evidence demonstrate that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).[5]

[5] Plaintiff argues that any deference to the Secretary's actions is inappropriate because, according to Plaintiff, the Secretary acted inconsistently. (Pl.'s M. for Summ. J. at 15). However, the Ninth Circuit has held that the Secretary does not act inconsistently when claims are initially covered at a lower level of review and then denied at the highest level of review. *Int'l Rehab. Sci., Inc. v. Sebelius*, 688 F.3d 994, 1000-01 (9th Cir. 2012). Plaintiff's reliance on *Malcomb v. Island Creek Coal Co.*, 15 F.3d 364, 369 (4th Cir. 1994), is misplaced. There the court found impermissible inconsistency in the Board's interpretation of cross-appeal regulations, where the Board interpreted its regulations differently in individual cases without explanation. *Id.* at 367-69. Here, however, the Secretary

VI. ANALYSIS

Because the MAC reached the decision that the BIO-1000 was not "reasonable and necessary for the diagnosis or treatment of illness or injury," it denied coverage of the device by Medicare. *See Int'l Rehab.*, 688 F.3d at 998. The Ninth Circuit upheld that conclusion. *Id.* at 996. Plaintiff now argues that it did not know and had no reason to know that the BIO-1000 would not be covered by Medicare, and, therefore, the Secretary must cover the denied claims as provided in 42 U.S.C. § 1395pp(a).[6] Plaintiff thus challenges the MAC's four decisions declining to indemnify RS Medical. Plaintiff asserts that it had no notice of non-coverage as provided in 42 C.F.R. § 411.406(e)(1) and (3), and, in addition, Plaintiff argues that there were a number of reasons for Plaintiff to assume that the BIO-1000 would be covered. Plaintiff's arguments are analyzed in detail below.

A. Whether Plaintiff knew or had a reason to know that the BIO-1000 would not be covered

1. Payment of Prior Claims

Plaintiff contends that it had no reason to believe that the claims at issue would not be covered by Medicare in the period between June, 2005 and March, 2007. Plaintiff points to the fact that many claims for its device, the BIO-1000, were covered between 2005 and 2006. Plaintiff here refers to the decisions to approve claims for the BIO-1000 that were made by Medicare contractors at the lower level of review. Plaintiff argues that because some claims were covered at the lower level, Plaintiff could not have known that the Secretary would deny the coverage at the highest level of review.

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applied the same standards of review to every claim ("reasonable and necessary"), and consistently denied claims at the final level of review with explanations as to why the claims were denied. *See Int'l Rehab. Sci. Inc.*, 688 F.3d at 1000-01.

[6] According to 42 U.S.C. § 1395pp(a), the Secretary must cover the denied claims if "both [beneficiary] and . . . provider of services . . . did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services . . . ."

In pertinent part, 42 C.F.R. §§ 411. 406(e)(1) and (3) state that a supplier has actual or constructive knowledge of non-coverage based upon "[i]ts receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from Medicare contractors" and "[i]ts knowledge of what are considered acceptable standards of practice by the local medical community." Plaintiff contends that it is inconsistent for the Secretary to grant Medicare coverage for the BIO-1000 at the lower levels of review, but then deny the coverage for the same device at the final level of review. Therefore, Plaintiff argues, it cannot be charged with knowledge based on non-acceptance by the medical community[7] and receipt of CMS notices.[8] In addition, Plaintiff contends that because the Secretary acted inconsistently, the Secretary's actions were arbitrary and capricious, and, therefore, the decision not to indemnify Plaintiff should be set aside as provided in 5 U.S.C. § 706.

The Court rejects Plaintiff's arguments. First, the Ninth Circuit found that the Secretary did not act in an arbitrary and capricious manner when Medicare approved coverage of the device in some claims, while denying coverage of the same device in other claims. *Int'l Rehab.*, 688 F.3d at 1001. The Ninth Circuit explained that "not all agency inconsistency is impermissibly arbitrary—only '[u]nexplained inconsistency.'" *Id.* (citing *Marmolejo-Campos v. Holder*, 558 F.3d 903, 914 (9th Cir. 2009)). The Ninth Circuit further explained that inconsistency is deemed arbitrary and capricious "only in 'rare instances, such as when an

[7] Plaintiff also argues that the Secretary incorrectly concluded that there was not enough evidence to show that the BIO-1000 was accepted by medical community. Plaintiff points to the fact that 4000 individual physicians prescribed the device to their patients (AR 20903). However, Medicare Program Integrity Manual ch. 13, § 7.1 specifically states that acceptance by individual physicians or group of physicians is not sufficient evidence of acceptance by medical community.

[8] The MAC's four final decisions to deny coverage of the device were all based on the exclusionary provision described in 42 U.S.C. § 1395y(a)(1)(A) that the device is not reasonable and necessary. Plaintiff should have known that the device would be deemed not reasonable and necessary because it was responsible for knowing the acceptable standards of practice, which indicated that the device was not within such standards. (*See* Defendant's list of Exhibits in support of motion for summary judgment, Doc.# 139, Ex. C at 6, Medicare Claims Processing Manual, ch. 30, § 40.1.3, which states that "suppliers are always responsible for knowing locally acceptable standards of practice.").

agency provides no explanation at all for a change in policy, or when its explanation is so unclear or contradictory that [the court is] left in doubt as to the reason for the change in direction." *Id.* (citing *Marmolejo-Campos*, 558 F.3d at 914). Here, it is clear that Medicare approved claims for the BIO-1000 only at lower levels of review, while it consistently denied claims at the highest level of review. These varying coverage decisions are not arbitrary and capricious.

In addition, Health Care Financing Administration (HCFA) Ruling No. 95-1-30 provided notice to Plaintiff regarding "an acceptable standard of practice" as to coverage decisions. (Def.'s M., Ex. B at 16). The Ruling states that a supplier must know "locally acceptable standards of practice." HCFA Ruling 95-1-30 (Def.'s M., Ex. B at 16). The Ruling further states that the knowledge of acceptance by local medical community is derived from "published medical literature," which "refers to scientific data or research studies that have been published in peer review medical journals . . . ." *Id.* In addition, MPIM ch. 13 § 7.1 "requires a claimant to show that a device is safe and effective through 'published authoritative evidence' such as 'definitive randomized clinical trials." *Almy*, 679 F.3d at 305.

The MAC provided an explanation as to why it found that RS Medical knew or had reason to know that the device would not be covered. The MAC based its decision on 42 C.F.R. §§411.406(e)(1) and (3) stating that "[the BIO-1000] efficacy had not been established in the requisite peer-reviewed literature" and "the record does not indicate general acceptance of the device by the medical community." (AR 39-40). Specifically, the MAC found that the studies offered by RS Medical showing "the effectiveness [of the BIO-1000] at alleviating pain" were not sufficient evidence because "among other methodological flaws,[9] they had been authored or

[9] The MAC reviewed the studies associated with the BIO-1000, which were submitted to it by BioniCare, and concluded that "five studies included no analysis and were conclusory, eight did not discuss the type of electrical stimulation treatment for which the BIO-1000 was prescribed, two studies had small sample sizes, one study was not randomized or double-blind, and one study lacked the proper control group." *Almy*, 679 F.3d at 306. Other methodological flaws included: the article was co-authored by a BioniCare Medical Consultant and BioniCare's

sponsored by the BIO-1000 manufacturer." *Int'l Rehab.*, 688 F.3d at 998-99 (AR 13-14; 38-39). As provided in the HCFA Ruling 95-1-30, and in the MPIM ch. 13, § 7.1, such evidence was not sufficient to establish acceptance by medical community. Also, as provided in MPIM ch. 13, § 7.1, the fact that individual physicians prescribed the device was not sufficient evidence that the device was accepted by the medical community. Medical Program Integrity Manual (MPIM) ch. 13, § 7.1 states that:

> [a]cceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community.

(AR 34).

2. The Award of the Billing Code and the Fee Schedule

Next, Plaintiff argues that it did not know and had no reason to know that the BIO-1000 was not covered by Medicare because the device received a Healthcare Common Procedure billing code E0762,[10] which has an associated fee schedule. Plaintiff cites to Government Accountability Office (GAO) report 03-175, which states that "Medicare covered about 99 percent of the procedures and devices that were assigned codes by an American Medical Association panel or a committee of insurers in 2001." (Pl.'s Reply, at 16, fn. 6).[11] Plaintiff also argues that it had a reason to believe that the award of the billing code indicated coverage

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President and three other physicians; "is not dated nor does it indicate when or whether the results of the study that it describes were initially published." The article describing the experiments on animals that "does not purport to correlate the results of the rabbit studies to the repair of human cartilage" (AR 13-14).

[10] Healthcare Common Procedure is a billing process established and used by Medicare and Medicaid Services to describe the specific items and services provided in the delivery of healthcare. It facilitates a uniform system to process claims in an orderly and consistent manner. Durable Medical Equipment is processed under the level II HCPCS codes. The supplier of the Durable Medical Equipment bills Medicare using this billing system. HCPCS Coding Question, Center for Medicare and Medicaid Services, http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCS_Coding_Questions.html (last visited Feb. 6, 2015).

[11] The Court takes judicial notice that the entire report is available at: www.gao.gov/products/GAO-03-175. The report does not help Plaintiff's argument regarding the issuance of a billing code because the report was not making a connection between the assignment of a billing code and Medicare coverage, but merely provides statistical data for a specific year that "Medicare covered about 99% of the . . . devices that were assigned codes . . . in 2001."

because it "designates the payment category, and it facilitates coverage and billing communications." (Pl.'s M. for Summ. J. at 20).

Plaintiff's argument is unpersuasive. The Ninth Circuit reviewed this issue on appeal and explained that:

> [t]he fact an item receives a billing code or fee schedule does not mean it is covered by Medicare, as the billing code and fee schedule manuals caution. Rather, the purpose of those codes and schedules is to promote uniform reporting and statistical data collection. They are used not only by Medicare, but also by private insurers and state Medicaid programs.

Int'l Rehab., 688 F.3d at 1004.

The Ninth Circuit also referred to the Fourth Circuit decision regarding the identical issue stating that "the fact that the BIO-1000 had received a billing code and fee schedule does not undermine the substantial evidence supporting the Medicare Appeals Council's coverage denials". *Id.* (citing *Almy v. Sebelius*, 679 F.3d 297, 307 n.3 (4th Cir. 2012)). Therefore, the fact that the BIO-1000 received a billing code and associated fee schedule did not warrant a conclusion that the device would be covered by Medicare.

3. Testimony by Thomas M. Zizic, President of the Manufacturer of the BIO-1000

In support of its argument that it did not know and had no reason to know that the BIO-1000 would not be covered by Medicare, Plaintiff points to the testimony of Thomas M. Zizic. Zizic testified that from meetings with Medicare contractors, which he began attending in May 2004, he understood that the contractors "believed that the evidence supported the clinical efficacy of the device." (AR 20912).

However, Zizic's subjective understanding of what he perceived the contractors believed is not the criterion for coverage of the device. The standard of review of the medical devices for Medicare purposes is set out in the Medicare Program Integrity Manual (MPIM). The Manual provides that when individual claims are being reviewed, the contractors must use the

"reasonable and necessary" standard. MPIM ch. 13, § 5.1 (AR 9). Further, the Manual provides the description of evidence that should be submitted in support that the device is reasonable and necessary. MPIM ch. 13, § 7.1 9 (AR 9). The evidence includes the "published authoritative evidence" or "general acceptance by medical community." *Id.* In addition, the Manual states that "limited case studies distributed by sponsors with a financial interest in the outcome are not sufficient evidence of general acceptance by the medical community." *Id.* (AR 10). These provisions provided notice to Plaintiff that its device was not covered by Medicare. Thomas M. Zizic's subjective understanding did not provide a reasonable basis for belief that the BIO-1000 was covered by Medicare. In addition, Zizic testified that the contractors denied nearly all of the BIO-1000 claims submitted in 2004 and 2005. (AR 19,135-38). When Plaintiff contracted with BioniCare to sell the BIO-1000 in 2005, BioniCare notified Plaintiff that Medicare Contractors had consistently denied coverage. (AR 19137-38). Therefore, Plaintiff knew that Medicare Contractors had denied nearly all of the BIO-1000 claims for at least two years. Also, in 2005, the denials by Medicare Contractors were based on the finding that the BIO-1000's effectiveness in healing osteoarthritis of the knee was not documented in appropriate studies. (Def.'s M. for Partial Summ. J. at 12). Finally, in 2005-2006, in order to obtain coverage of the device, Plaintiff submitted two letters to the Center of Medicare and Medicaid Services from Senators Arlen Specter, Rick Santorum, and Patty Murray, in which the Senators express their concern that the CMS consistently denied coverage of the BIO-1000. (AR 20,902; 20,899). Based on this record, Plaintiff knew or should have known coverage was systematically denied and would be denied in the future.

4. FDA Clearance

Next, Plaintiff argues that the fact that the Food and Drug Administration cleared the BIO-1000 as "safe and effective" created a reasonable basis for Plaintiff to believe that the

device would be covered by Medicare. Specifically, Plaintiff contends that because the BIO-1000 was found substantially equivalent to the TENS device, which was covered by Medicare, Plaintiff had a reason to believe that the BIO-1000 would also be covered.

Such a belief on Plaintiff's part was unjustified. The Ninth Circuit has held that "FDA clearance . . . is necessary, but not sufficient for Medicare coverage. *Int'l Rehab.*, 688 F.3d at 1002 (citing 68 Fed. Reg. 55,634, 55,636 (Sept. 26, 2003)). The court further stated that:

> FDA review and Medicare coverage review have different purposes. FDA review seeks to determine whether a device is "safe and effective" such that it can be marketed to the general public. By contrast, Medicare coverage review seeks to determine whether the device is "reasonable and necessary" for treatment such that the device is worth the government's money.

Id. (citing *Medicare Benefit Policy Manual*, ch. 15, § 110.1[C][2]).

In addition to FDA clearance, Medicare coverage depends on other criteria as well, for example, "whether there are less costly but equally effective devices available." *Id.* For example, the TENS unit (devices similar to the BIO-1000) are used to treat the osteoarthritis of the knee and cost less than $800. *Int'l Rehab.*, 688 F.3d at 998. On the other hand, "RS Medical charges more than $4000 for a single-knee BIO-1000 and more than $5000 for a dual-knee BIO-1000." *Id.* As such, Plaintiff should have been aware that the "substantial equivalence" of the BIO-1000 to the TENS device did not guarantee Medicare coverage.

B. Whether Plaintiff successfully shifted liability to the beneficiaries.

Finally, Plaintiff argues that, even if it knew or should have known Medicare would deny coverage of the device, it issued Advance Beneficiary Notices to the beneficiaries sufficient to provide the beneficiaries with notice of non-coverage and, thus, shifted the risk of liability to the beneficiaries. The ABN at issue stated: "Medicare has not established coverage criteria for this

item or does not cover this item." (AR 19,217).[12] Plaintiff argues that this ABN was effective to provide the notice of non-coverage to the beneficiaries because it was on a CMS-approved form, because it specified the BIO-1000 as the product, and because it specified the reason of non-coverage that 'Medicare has not established coverage criteria." (AR 19217).

The MAC found that "this ABN is equivocal in its assessment of coverage for the device. Accordingly, the beneficiary did not receive adequate notice that the item would not be covered, and the beneficiary's liability is waived pursuant to section 1879." (AR 19, 218). Instead of providing a specific reason why coverage is unlikely, this ABN simply states that Medicare will probably not pay because there is no Medicare coverage, or because there is no coverage criteria. 42 C.F.R. § 411.404(b) provides: "[a] beneficiary is deemed to have knowledge of non-coverage if the supplier provides written notice to the beneficiary explaining why it believes that Medicare will not cover the item or service." In addition, Medicare Claim Processing Manual states that in order to provide the beneficiary with sufficient notice, the supplier must write in the body of the ABN "a genuine reason that denial by Medicare is expected." (Def.'s M., Ex. C at 17 (Medicare Claims Processing Manual ch. 30, § 40.3.6.1)). The Manual also states that "a generic ABN does no more than state that Medicare denial of payment is possible, or that the notifier never knows whether Medicare will deny payment." *Id.* As the United States District Court for the District of Maryland has already found, Plaintiff's did not provide the beneficiaries with the necessary detail or context for why coverage of the BIO-1000 might be denied. See *Almy v. Sebelius*, 749 F.Supp.2d 315, 334-35 (D. Md. 2010). In *Almy*, the Court considered substantially similar ABNs and found that the Secretary's decision that "the supplier's ABN was a generic statement that

[12] Plaintiff was successful, at the MAC level, in shifting some of its liability to beneficiaries because of an ABN that it issued. The effective ABN stated: "BIO-1000 System is a newly released product which has not yet received certification from Medicare as a covered benefit/product for treatment, and, therefore, may be considered experimental." (AR 19,989). The MAC found that this notice "constituted adequate prior written notice that Medicare would not cover the device," and concluded that "[t]he beneficiary [was] therefore liable under section 1879 of the Act." (AR 19,989).

does not provide sufficient details concerning the genuine reason that denial by Medicare is expected" was supported by substantial evidence. *Id.* Therefore, beneficiaries could not "make an informed consumer decision about receiving items or services for which they may have to pay out-of-pocket." *Int'l Rehab.*, 688 F.3d at 998. Thus, because the ABNs at issue did not provide beneficiaries with adequate notice that the BIO-1000 would not be covered by Medicare, the Secretary correctly declined to shift liability from Plaintiff to the beneficiaries.[13]

VII. CONCLUSION

For the foregoing reasons, the Court GRANTS Defendant's Motions for Partial Summary Judgment and DENIES Plaintiff's Motion for Summary Judgment. All issues having been resolved by the Court's order, this case is DISMISSED.

BARBARA J. ROTHSTEIN
UNITED STATES DISTRICT JUDGE

[13] Plaintiff argues that it only issued ABNs to protect itself from unpredictable decisions by the agency at various levels of review. As such, according to Plaintiff, these ABNs should not be used as evidence that Plaintiff should have known Medicare would not cover the device. However, the regulation is clear that if a supplier notifies beneficiaries that the device will not be covered by Medicare, the supplier is considered to know that the device will not be covered by Medicare. 42 C.F.R. § 411. 406(b)(1). In addition, Plaintiff argues that 42 C.F.R. § 411. 406(b)(1) should not be considered at all because the Secretary based her decision to charge Plaintiff with knowledge of non-coverage on 42 C.F.R. 411.406(e)(1), (3). However, the Secretary referred to § 411. 406(b)(1) as one of the grounds not to indemnify Plaintiff in all of her four decisions that are at issue in this case. Plaintiff may not have it both ways: to shift liability with clear statement that Medicare will not cover the device, and at the same time plead ignorance that Plaintiff lacked knowledge that Medicare would not cover the device.